



USAID
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CD4 MACHINE LOGISTICS FACT SHEETS

FACSCOUNT™



MANUFACTURER INFO

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MATERIALS PROVIDED WITH START-UP PACKAGE

- dedicated instrument system for CD4, CD8, and CD3 absolute counting
- automated analysis software (available for CD4/CD8 or only CD4)
- coring station
- electronic pipette
- workstation for holding blood samples and supplies during sample and control preparation
- spares kit containing replacement parts and consumables.

OPTIONS

- barcode reader

MATERIALS NOT PROVIDED WITH START-UP PACKAGE

- vortex mixer

MATERIALS REGULARLY CONSUMED

- FACS Flow (Catalog No. 342003)
- FACS Clean (Catalog No. 340345)
- FACS Rinse (Catalog No. 340346)
- FACS Control Kit (Catalog No. 340166)
- pipette tips
- K₃ or K₂ EDTA BD Vacutainer™ brand blood collection tubes
- disposable gloves
- chlorine bleach
- distilled water
- biosafety materials.

PRECISION/REPORTABLE RANGE

- <10% coefficient of variation for:
CD4 results between 50 and 2,000
CD8 results between 100 and 2,000
CD3 results between 100 and 3,500.

RESULTS PROVIDED

- CD4 absolute count
- CD8 absolute count
- CD3 absolute count
- CD4/CD8 ratio
- CD4/CD3 ratio (if using single tube CD4 software/reagents)
- (no CD4 percentage capability).

TIME TO RESULT

- 70 minutes (5 minutes for preparation, 60 minutes for incubation, 5 minutes for instrument run)
- maximum sample throughput:
 - >15 patients/hour for CD4 ≥ 400 (fewer patients/hour with lower CD4 count)
 - >30 patients/hour for CD4 ≥ 400 (if only using single tube for CD4)
- maximum samples per run: 1.

SPACE REQUIREMENTS

Instrument:

- Width: 43.2 cm (17 in)
- Height: 38.1 cm (15 in)
- Depth: 55.9 cm (22 in)
- Weight: 25.9 kg (57.1 lbs) (when fluid reservoirs are empty).



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Workstation:

- Width: 48.3 cm (19 in.)
- Height: 9.1 cm (3.6 in.)
- Depth: 18.5 cm (7.3 in.)

REGULATORY STATUS

- Approved by FDA for in vitro diagnostic
- Single tube for CD4: for export only, not for sale or distribution in U.S.

REAGENT AND QUALITY CONTROL COMMODITY INFORMATION

Reagents (2 reagent kits are available):

- CD4/CD8 reagent kit
 - Includes: premeasured CD4/CD3 reagent tubes, premeasured CD8/CD3 reagent tubes, counting beads, tube caps, and fixative
 - Available in 50 tests/kit
 - Two premeasured reagent tubes and counting beads required per test (CD4/CD3 and CD8/CD3)
- Single tube CD4 reagent kit
 - Includes: premeasured CD4/CD3 reagent tubes, counting beads, tube caps, and fixative
 - Available in 50 tests/kit
 - One premeasured reagent tube and counting beads required per test (CD4/CD3)

Quality controls:

- Control bead kit (use daily)
 - Includes: zero, low, medium and high concentrations of control beads
 - Available in 25 runs/kit
 - Two reagent pairs (4 tubes for CD4 and CD8, 3 tubes for single tube CD4) plus control beads required per control run

COST

- Instrument: \$27,000*
- Reagents:
 - CD4/CD8: \$6/test*
 - Single Tube CD4: \$4.50/test*
- Quality Controls: \$7-8.80/run,* depending on volume (slightly cheaper for single tube CD4)
 - * Average price in Africa. Excludes freight, duties, taxes, and distribution.

SHELF LIFE

Reagents

- 15 months from manufacture
- Reagents are guaranteed to have 6 months shelf life when leaving San Jose, Puerto Rico, and 5 months when arriving in Africa.

Quality controls

- 18 months from manufacture
- Reagents are guaranteed to have 7 months shelf life when leaving San Jose, Puerto Rico, and 6 months when arriving in Africa.

STORAGE REQUIREMENTS

Conditions for reagents and quality controls:

- 2–8°C (36–46°F)

Packaging:

- Reagents
 - Width: 18.7 cm (7.4 in.)
 - Height: 18.4 cm (7.3 in.)
 - Depth: 10.3 cm (4.1 in.)
- Quality Controls
 - Width: 18.7 cm (7.4 in.)
 - Height: 4.3 cm (1.7 in.)
 - Depth: 12.7 cm (5 in.)

SAMPLE INFORMATION

Blood stability:

- 48 hours after drawn if stored at room temperature

Sample stability:

- 48 hours after preparation when stored at room temperature

Blood sample volume required:

- 100 µL (50 µL for single tube CD4)

OPERATIONAL CONSIDERATIONS

- Software and reagents are available for single tube CD4 tests (CD4/CD3 only) to reduce cost; software for CD4/CD8 capability and for CD4-only capability cannot run concurrently.
- Includes 1 day of onsite installation and training.
- Includes computer-based training and user's guide.
- Strong technical support, including an Africa-based technical assistance unit.
- Regional workshops on good laboratory practice are offered.
- Minimum order of 20 kits offers the best value for shipping, but there is no required minimum order.
- One year warranty (costing \$5,000) includes two preventative maintenance visits and two urgent repair visits.
- Additional visits are invoices for travel costs only; defective parts replaced free of charge.
- This technology does not offer CD4 percentage.

The author's views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

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